Senate Committee on Environment and Public Works
Hearing Entitled, *"Hearing on the Nominations of Shannon Estenoz to be Assistant Secretary of Fish and Wildlife and Parks of the Department of Interior, Radhika Fox to be Assistant Administrator for Water of the Environmental Protection Agency, and Michal Freedhoff to be Assistant Administrator for Chemical Safety and Pollution Prevention of the Environmental Protection Agency."*
May 12, 2021
Questions for the Record for Michal Freedhoff

Senator Kelly:

1. If confirmed, you would play a role in developing regulations which would govern the discharge and cleanup of PFAS. High levels of PFAS has been detected in several groundwater aquifers near Arizona military installations This is particularly concerning to me because every groundwater aquifer in Arizona could be used for drinking water – and as the Colorado River looks likely to enter a Tier 1 shortage this year, Arizona will be more dependent than ever on our groundwater supplies. If confirmed, how will you approach regulations related to PFOA and PFOS?

    a. In particular, how will you ensure that EPA supports communities that are disproportionately dependent on drinking water from closed-source aquifers?

Response: As I stated at my nomination hearing, addressing PFAS and emerging contaminants will be a top priority of mine if confirmed as Assistant Administrator for the Office of Chemical Safety and Pollution Prevention.

While drinking water is not in my portfolio, EPA's chemical safety office is working on several PFAS initiatives that will help gather data and allow EPA to focus research and monitoring efforts to prioritize PFAS actions. First, we are requiring certain facilities to report to EPA releases of nearly 200 PFAS into the environment. Second, EPA has drafted a proposed rule that would require any company that manufactured PFAS since 2011 to tell EPA what they made, how much they made and what it was used for. This would also help focus EPA's monitoring and regulatory efforts. Third, EPA recently announced its expectation that new PFAS will generally not qualify for certain exemptions from TSCA's pre-manufacture notice review process going forward.

As we continue along this process, I am committed to a flexible approach and to working collaboratively with all stakeholders on the impacts of PFAS. The specific characteristics of Arizona communities you have highlighted are good examples of the types of information EPA will consider as we move forward in the regulatory process.

2. I wanted to ask for your thoughts on the broader precedent that might be set for EPA's pesticide program from the recent court ruling in the 9th Circuit. In the 2-1 ruling, the Court superseded EPA's scientific interpretation it used to reject a petition and mandated EPA take specific regulatory actions based on the Court's scientific interpretation. I am concerned this precedent will direct how EPA must treat petitions for any chemistry

moving forward. In order to withstand judicial scrutiny, EPA's career scientists may have to conduct significant reviews of all petition claims regardless of their expert assessment of the petition's underlying science. Has EPA considered these potential longer-term impacts in its decision on how to respond to the Court's ruling?

Response: Chlorpyrifos is a pesticide that is known to cause neurological harm at unsafe exposure levels, and is of great concern especially to the farmworkers and their families. EPA is reviewing the decision as it considers its options regarding the decision.

As the agency pursues its mission to protect human health, including that of children, and the environment, if confirmed, I commit to ensuring that registered pesticides do not cause unreasonable adverse effects on human health and the environment, helping support and protect farmworkers and their families while ensuring pesticides are used appropriately among the nation's agriculture, and ensuring EPA continues to use sound science in the decision-making process under the Federal Insecticide, Fungicide and Rodenticide Act.

Ranking Member Capito:

1. The Toxic Substances Control Act (TSCA) defines "conditions of use" as the circumstances under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of. What is the difference between a "reasonably foreseen" use and "any possible" use?

Response: If confirmed, I commit to implementing TSCA within the statutory requirements as written by Congress. In implementing TSCA, EPA bases "reasonably foreseen" use on information, knowledge, and experience, and not on any conceivable condition of use.

EPA indicated in its rulemaking entitled "Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act" that "the identification of `reasonably foreseen' conditions of use will necessarily be a case by case determination, and will be highly fact-specific. Sources of facts to support such determinations may include known activities associated with similar chemicals, knowledge of a chemical's properties that may allow it to replace a function currently being performed by non-chemical means, or information on research and development activities applying a chemical substance to a particular new use. It is reasonable to foresee a condition of use, for example, where facts suggest the activity is not only possible but, over time under proper conditions, probable." (82 FR 33730-31)

2. EPA evaluates potential pesticide risks under the Food Quality Protection Act, which requires a "reasonable certainty that no harm will result" from exposure to determine a pesticide is safe. Under TSCA, the risk standard is that the chemical is "not likely to present an unreasonable risk of injury to health or the environment." What is the difference in certainty between "not likely to present an unreasonable risk" and "reasonable certainty that no harm will result"?

Response: If confirmed, I commit to implementing EPA programs within their statutory requirements as written by Congress. The FQPA amended the Federal Insecticide, Fungicide and Rodenticide (FIFRA) and the Federal Food, Drug, and Cosmetics Act (FFDCA) to address, among other things, setting limits on the amount of pesticide residues that may remain in or on foods marketed in the U.S. In contrast, TSCA covers chemical substances manufactured, processed, distributed in commerce, used or disposed of for commercial purposes in the U.S. and explicitly excludes from the definition of "chemical substance" any pesticide (as defined in FIFRA) and any food, food additive, drug, cosmetic, or device (as defined in the FFDCA) when manufactured, processed, or distributed for use as such. The respective risk standards in various statutes are best interpreted within their own statute and body of caselaw, regulations and policies.

3. What steps will you take to ensure transparent coordination on chemical risk assessment and management between the Office of Chemical Safety and Pollution Prevention (OCSPP) and other EPA program offices or federal agencies?

Response: I believe it is important for all public servants to be as transparent as possible to Congress and to the public as we look at information and develop decisions for moving forward. If confirmed, I commit to conducting my office's work in a transparent manner, as we restore scientific integrity and evidence-based policymaking throughout EPA, including working with other EPA program offices and other federal agencies.

OCSPP has regular communications regarding chemical risk evaluations with EPA staff from ORD and other offices to provide updates and opportunities for review and comment. For existing chemicals in risk management, OCSPP follows EPA's processes for rulemaking, one of which is to form cross-agency workgroups that allow for input across the agency during the rule development. Additionally, we are engaging with the Occupational Safety and Health Administration, National Institute for Occupational Safety and Health, Department of Defense, National Aeronautics and Space Administration, and other federal agencies to leverage their expertise.

4. While the Office of Research and Development (ORD) leads the Agency's scientific research activities, the OCSPP is responsible for evaluating risks from chemicals. Other EPA program offices, as well as state regulatory agencies, also carry out research and data analysis activities. Findings among different offices may not converge on a single outcome. How will you handle instances of conflicting data or conflicting conclusions within EPA or between EPA and your state partners?

Response: In addition to the existing processes described in response to Question 3, EPA's Scientific Integrity Policy was issued in February 2012 and provides a framework to promote scientific and ethical standards and to create a proactive culture to support them. The policy explicitly welcomes differing views and opinions on scientific and technical matters as a legitimate and necessary part of the scientific process.

5. What do you believe is the appropriate role of the EPA's Integrated Risk Information System (IRIS) program in regulating chemicals and the risk assessment

and management process, and how do you intend to ensure ORD coordination with OCSPP staff?

Response: EPA's IRIS program assesses the human health hazards for chemicals of interest to EPA. In the case of TSCA existing chemical risk evaluations, IRIS assessments can serve to inform the human hazard assessment for chemicals being evaluated. However, TSCA risk evaluations must also "integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance."

Under TSCA, the Agency is required to use the best available science for many key Agency actions, whatever the source, so we routinely review and consider IRIS assessments in addition to other sources. However, the Agency will not rely solely on IRIS assessments for its TSCA activities, as that would not be consistent with the law. Put plainly, an IRIS assessment cannot substitute for a TSCA risk evaluation.

6. In a recent update to EPA's New Chemicals Program, EPA announced that it will no longer assume that workers are adequately protected under the Occupational Safety and Health Administration (OSHA) worker protection standards where EPA identifies a potential unreasonable risk to workers that could be addressed with appropriate personal protective equipment and hazard communication. What empirical evidence is EPA relying on to support the new approach of no longer assuming workers are adequately protected under the OSHA worker protections standards?

Response: EPA's New Chemicals program helps manage the potential risk to human health and the environment from chemicals new to the marketplace. If confirmed, I commit to ensuring necessary protections for workers. Decisions in the new chemicals program are made on a case-by-case basis. Conclusions regarding whether workers are or are not adequately protected under OSHA worker protection standards result from analysis of the applicable factual and legal conditions in each case. EPA can identify the absence of worker safeguards as "reasonably foreseen" conditions of use, and mandate necessary protections through a TSCA section 5(e) order, as appropriate. As a general matter, in 2020, violations of OSHA's respirator safety standards were third and violations of eye and face protection were ninth in OSHA's Top 10 Most Frequently Cited Standards, following inspections of worksites by federal OSHA. Please see https://www.osha.gov/top10citedstandards

7. A key driver for chemical innovation is to make chemicals that are safer or environmentally superior to the chemicals that they would replace.
   a. Is EPA able to evaluate whether a proposed new chemical would be safer than the chemical(s) that it would replace?
   b. If not, what prevents EPA from doing this evaluation?

Response: EPA's New Chemicals program helps manage the potential risk to human health and the environment from chemicals new to the marketplace. When new chemical submitters provide information adequate for considering the unique hazard and/or exposure characteristics for a chemical believed by the submitter to be safer than alternatives, EPA can incorporate this information into the risk assessment and/or risk management decisions for that chemical. In this

way, the program supports development of safer chemical substances by minimizing or eliminating regulatory burdens on new chemicals if they will replace riskier substances already in the marketplace.

8. You have publicly stated that you plan to reopen some or all of the first ten TSCA risk evaluations of existing chemicals by looking back "surgically at specific areas in some of the risk evaluations to supplement them as appropriate." More specifically, how will your office reopen and supplement these risk evaluations, while ensuring the process is open, transparent, involves stakeholder input, and does not create undue confusion and uncertainty?

Response: Congress showed leadership in passing much-needed changes to TSCA—America's primary chemical safety law. President Biden's *Executive Order 13990: Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis* requires EPA to review the last Administration's actions, including risk evaluations for chemical substances under TSCA. The Agency is evaluating whether to make any changes in specific areas of some of the risk evaluations to make sure that the risk evaluations and risk management rules (which must address unreasonable risks identified in the risk evaluations) are scientifically and legally defensible and that the rules are sufficiently protective. We would consider doing this surgically because the first 10 risk evaluations documented unreasonable risk under the majority of conditions of use across the first ten chemicals for workers, occupational non-users, consumers and bystanders, and thus already require risk management to address the unreasonable risk in order to protect human health and the environment. To ensure there are not gaps in the scope of the risk evaluation, it would be important to conduct additional analysis to ensure that potential unreasonable risks have not been overlooked.

9. TSCA provides EPA 90 days to review new chemicals, or with good cause for extension, 180 days. How many submissions does EPA currently have that were submitted greater than 90 days ago? 180 days?

Response: EPA's New Chemicals program helps manage the potential risk to human health and the environment from chemicals new to the marketplace. As of May 16, 2021, EPA has 240 applications that were submitted more than 90 days earlier (and of this total, there are 189 applications that were submitted more than 180 days earlier). However, none of these applications are outside the applicable review period. EPA's regulations at 40 CFR 720.75(b) allow submitters to request a voluntary suspension of the review period, and submitters often take advantage of this option in order to develop additional data or to continue discussions about their application with EPA.

10. Under TSCA, if EPA does not conclude its review on time, EPA is required to refund all charges to the submitter. Has EPA ever issued such a refund?

Response: TSCA section 5(a)(4) requires a refund of applicable fees in these circumstances, unless the submitter has not provided required information or has otherwise unduly delayed the process in a way that prevents timely determination. EPA in many cases grants a suspension of the review period requested by the submitter, which effectively puts the review period on

"pause" to allow the submitter to provide information to EPA to clarify the initial submission or to address risk identified by EPA after the initial risk assessment is completed. When the running of an applicable review period has been suspended, the lack of a determination within 90 days of receipt of a notice would not trigger a fee refund under TSCA section 5(a)(4). To date, EPA has not issued a refund for failing to make a determination on a notice by the end of the applicable review period.

11. In certain circumstances, EPA can request suspensions of the TSCA deadlines and request additional information. However, EPA has been increasingly requesting suspension of the TSCA deadlines without requesting additional information. If EPA requests a suspension of the TSCA deadlines but does not request additional information, and the submitter denies the suspension request, how would EPA proceed?

Response: EPA's regulations at 40 CFR 720.75(b) allow submitters to request a voluntary suspension of the review period, and submitters often take advantage of this option in order to develop additional data or to continue discussions about their application with EPA. Suspensions of new chemical reviews are requested by submitters of new chemical notices, most often when EPA has conducted a risk assessment for a new chemical and identified potential risks.

If confirmed, I look forward to learning more about this issue from the science and programmatic experts at EPA.

12. How many suspensions has EPA requested and how many of those were not accompanied by a request for additional information?

Response: EPA's regulations at 40 CFR 720.75(b) allow submitters to voluntarily suspend the running of the notice review period, and submitters often take advantage of this option in order to develop additional data or to continue discussions about their application with EPA. Please also see the response above.

13. Do you believe requesting the suspension without asking for additional information circumvents the deadlines in the statute?

Response: Section 5(e) of TSCA allows the Agency to issue orders when adequate information is not present. Issuing suspensions, at the submitters request, can benefit both submitters and the public. If confirmed, I commit to conducting the Agency's work in a transparent manner, as scientific integrity and evidence-based policymaking are restored throughout EPA, and look forward to learning more about this issue from the science and programmatic experts at EPA.

14. To prevent the government from slowing innovation, the previous Administration focused on reducing the backlog of new chemical applications, successfully reducing the new chemical backlog from over 450 cases to 183 cases by January 2021. What is the number of cases in the backlog today?

a. Do you expect the backlog to increase given EPA's recently announced policy changes to new chemical reviews?
b. How will you prevent increasing the backlog?

Response: EPA's New Chemicals program helps manage the potential risk to human health and the environment from chemicals new to the marketplace. In August 2017 it was announced that the "backlog" was eliminated, although there were 302-308 cases still under review (https://archive.epa.gov/epa/newsreleases/epa-eliminates-new-chemical-backlog-announces-improvements-new-chemical-safety-reviews.html). None of the cases in EPA's current queue (300 as of May 16, 2021) are outside the applicable review period. For any case that was submitted over 90 days ago, the review period has been voluntarily suspended at the request of the submitter pursuant to 40 CFR 720.75. For 73 of those 300 cases, EPA is awaiting submitter input. The remaining cases are in various stages of review, as shown on EPA's New Chemicals case tracker webpage (https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review).

15. How do you plan to communicate to the public what are real-world, expected risks versus risks generated by modeling and assumptions that reflect a worst-case scenarios?

Response: I believe it is important for all public servants to be transparent with the Congress and the public as we look at information and develop decisions for moving forward. As I said in my response to Chairman Carper related to worker safety, I also believe that the Agency could improve upon its TSCA risk communications efforts in order to provide the appropriate context for its risk evaluations.

If confirmed, I commit to conducting my office's work in a transparent manner, as we restore scientific integrity and evidence-based policymaking throughout EPA.

16. In a previous conversation with me, you acknowledged that not all PFAS are the same. Do you think EPA should analyze and regulate individual PFAS based on their particular health and environmental risks?

Response: President Biden highlighted the importance of and his commitment to tackling PFAS pollution and protecting public health and the environment. If confirmed, I commit to addressing PFAS as a top priority for EPA.

Consistent with TSCA, the chemical safety office assesses and regulates PFAS either individually or as groups/categories based on similarity in physical-chemical and biological properties, as deemed appropriate based on the availability of data/information and the regulatory context and decision being made. Grouping or category approaches for chemical assessment and regulation have been used under TSCA for both new and existing chemical assessment for decades.

In the legislative language authored by the Senate Environment and Public Works Committee and enacted in 2019, the Agency (through its Office of Research and Development, ORD) was given direction to

> *"(2) develop a process for prioritizing which perfluoroalkyl and polyfluoroalkyl substances, or classes of perfluoroalkyl and polyfluoroalkyl substances, should be subject to additional research or regulatory efforts that is based on—*
>
> *(A) the potential for human exposure to the substances or classes of substances;*
>
> *(B) the potential toxicity of the substances or classes of substances; and*
>
> *(C) information available about the substances or classes of substances;"*

I see great value and near-term applicability of ORD's work in this area.

17. Should PFAS ever be grouped and reviewed accordingly based on similar physical, chemical, and biological properties and, if so, what scientific reviews are necessary to ensure that a group of PFAS compounds pose the same health and environmental risks, if any?

Response: Generally, classes or sub-classes of substances are groupings based on similar structural, physical-chemical and/or biological properties.

The chemical safety office believes that grouping of PFAS based on similarity in structural, physical-chemical and biological properties is appropriate. Further, such grouping or category approaches have been used within OPPT for both new and existing chemical assessment for decades. This experience, and the emerging research conducted by ORD (as directed by Congress), as well as established approaches, for example as developed in the Organization for Economic Cooperation and Development (OECD), for developing scientifically sound chemical groups or categories, would be the basis for ensuring PFAS groups or categories are scientifically sound.

18. During your nomination hearing before the Committee, you acknowledged that there are gaps in EPA's PFAS research that need to be filled. What are the remaining PFAS research gaps that need to be resolve before the Agency is able to move forward with additional regulatory actions?

Response: President Biden highlighted the importance of and his commitment to tackling PFAS pollution and protecting public health and the environment. If confirmed, I commit to addressing PFAS as a top priority for EPA.

While extensive research exists for some PFAS, that is not the case for all of them. The efforts underway at EPA, which draw in part from legislation authored by the Senate Environment and Public Works Committee, are designed to strategically focus our research, monitoring and

regulatory efforts on the PFAS that have been identified as being of concern due either to their potential hazard or presence in the environment.

19. What is a simple chemical description that is common to and describes all PFAS compounds?

Response: OPPT applies the following "working definition" when identifying PFAS on the TSCA Inventory: a structure that contains the unit R-CF2-CF(R')(R"), where R, R', and R" do not equal "H" and the carbon-carbon bond is saturated (note: branching, heteroatoms, and cyclic structures are included). This definition may not be identical to other definitions of PFAS used within by EPA and/or other organizations."

20. Given this Administration's policy of evidence-based decisions supported by the best available science and data, how would you handle a situation where staff work relies on a scientific study that is missing critical information to support its findings?

Response: OCSPP uses Systematic Review to search for and evaluate the quality and completeness of scientific studies used for TSCA Risk Evaluations. The resulting risk evaluation, including the assessment of the underlying body of evidence, is subject to a rigorous external and independent peer review to ensure that the results meet the bar of best available science. In addition, TSCA risk evaluations are subjected to public comment, which present opportunities to submit studies that commenters believe the Agency has overlooked or where they have concerns with our use of specific studies.

If confirmed, I commit to conducting my office's work in a transparent manner, as we restore scientific integrity and evidence-based policymaking throughout EPA, including relying on the best available science.

Senator Inhofe:

1. Dr. Freedhoff, as EPA continues implementing the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, it is fundamentally important that the EPA safeguard private stakeholders' confidential business information. Protecting America's confidential business information is vital to global competitiveness and national security. We cannot allow countries like China access to sensitive business information. Will you ensure the regulated community has ample time to ask questions and make corrections to any sensitive business information that will be shared publicly by EPA?

Response: If confirmed, I commit to transparency while fulfilling responsibilities under TSCA. Under TSCA, EPA collects a range of information and in some cases the law allows some of it to be claimed as confidential business information (CBI). EPA is respectful of CBI, the release of which may cause substantial business injury to the owner.

EPA has established new processes, systems, and procedures to enable submitters to provide the information required when making confidentiality claims and to facilitate EPA's review, and where applicable, determinations on these claims.

2. Dr. Freedhoff, it is fundamentally important that the EPA continually engage the private stakeholders it is regulating. As you know, the EPA is currently conducting a public comment period on five final rules for persistent, bioaccumulative toxic chemicals previously issued on January 6, 2021, under TSCA. I am aware of concerns that these rules may pose challenges for retailers, who are newly subject to potentially strict liabilities and high penalties for the sale of "articles" containing these chemicals. However, it is my understanding that these rules may not provide retailers with the information they need to take action related to these articles. Has EPA conducted outreach to the retail community to seek their input on the best way to enable their participation in these new rules?
    a. Will you commit to working with retailers to ensure they are provided with the supply chain information they need to implement the intended sales restrictions on articles?
    b. And will you commit to improving stakeholder engagement as you continue implementation of TSCA?

Response: I believe it is important for all public servants to be as transparent as possible to Congress and to the public as we look at information and develop decisions for moving forward. If confirmed, I commit to conducting my office's work in a transparent manner, as we restore scientific integrity and evidence-based policymaking throughout EPA.

Regarding persistent, bioaccumulative and toxic (PBT) chemicals, if confirmed, I commit that before making a decision on next steps, EPA will review public comments received in response to the Agency's request for comment on the final PBT rules. We encourage members of the public to provide comments on the final rules including whether there are further exposure reductions that could be achieved, including for potentially exposed or susceptible subpopulations and the environment; implementation issues associated with these final rules; and whether to consider additional or alternative measures or approaches such as requiring personal protective equipment.

3. Dr. Freedhoff, there are a number of measures that we must take to eradicate the COVID-19 pandemic. Vaccinations are an important and effective measure against the virus but there are additional measures that can be utilized to reduce the spread of COVID-19, including through long-lasting disinfectants. Long-lasting disinfectants minimize the required number of regular disinfectant applications, thereby reducing the potential negative health impacts that come from over application of regular disinfectants. Allied BioScience (ABS), a biotech firm, created "SurfaceWise2", which is a continuously active antiviral surface coating that kills viruses, including SARS-CoV-2. Accordingly, ABS has submitted an application for nationwide use of the product under the standard authority laid out in Section 3 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). If approved for use, Americans would have access to a long-lasting disinfectant

that has been approved by EPA for residual efficacy of up to 30-days. When do you expect the final Section 3 approval process to be completed?

a. Are there any steps you can take to expedite the regulatory review process?
b. And will you please keep my staff updated on EPA's review and actions related to this application?

Response: In order to respond to the public's needs over this past year of the pandemic, EPA expedited review and approval of surface disinfectant products for use against SARS-CoV-2, the coronavirus that causes COVID-19, created List N, a public listing of products expected to be effective against SARS-CoV-2, and then added over 500 products to it. Over the course of the last year, EPA reacted to unprecedented circumstances by activating its Emerging Viral Pathogens guidance, minimizing disinfectants supply chain disruptions through regulatory flexibilities, releasing new and updated scientific protocols, and providing several pathways for expedited review. If confirmed, I commit to continue to follow the evolving science of the pandemic by shifting resources to the evaluation of novel products, such as those that kill airborne SARS-CoV-2; to meet critical deadlines in the registration and review of all pesticide products within EPA's purview; and to keep Congress informed on EPA actions, including communicating with your office regarding Allied BioScience's application for registration of their SurfaceWise2 product.

Senator Cramer:

1. Dr. Freedhoff, North Dakota is home to the most innovative and resilient agricultural producers. These producers operate on tight margins in order to provide the highest quality food, fuel, and fiber in the world. Unfortunately, producers are reluctant to commit to long-term purchases of chemical products because of the fear that the products or components could be revoked or altered at any time, leaving them with purchased product they are unable to use. The agricultural community has expressed a strong interest in the Environmental Protection Agency (EPA) maintaining an independent, predictable, science-based, and risk-based regulatory process for pesticides that generates continuity and reliability for their operations. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Congress granted EPA the authority to determine pesticide safety. EPA's Office of Pesticide Programs is staffed by scientists that work to ensure each registration label is underpinned by sound science with respect to human health and the environment. You are no doubt aware of the recent ruling in LULAC v. EPA. I am concerned the potential precedent this ruling might set and the impact it may have on EPA's pesticide program. If a court can place its own scientific interpretation over EPA's, that could undermine EPA's authority to make independent, science-based decisions, and might require EPA to invest significant resources to review petition claims in the future to ensure decisions withstand judicial scrutiny.
    a. Is EPA concerned about the potential of this precedent and considering potential long-term impacts in its response to the ruling?
    b. Should the frequency of petitions increase or if EPA must invest additional staff work into their consideration moving forward, does EPA have the capability to conduct additional petition work without significant disruptions to the pesticide program?
    c. How will you work with EPA's Office of General Counsel and the Justice Department to defend the science behind existing pesticide registrations, of which EPA career

scientists within the Office of Pesticide Programs work to underpin with sound science?

d. Do you believe the pesticide program should be stable and predictable?

e. Should you be confirmed, how will you work with producers and industry to provide certainty and consistency to the pesticide program?

Response: Chlorpyrifos is a pesticide that is known to cause neurological harm at unsafe exposure levels and is of great concern especially to the farmworkers and their families. EPA is reviewing the decision as it considers its options regarding the decision.

As the agency pursues its mission to protect human health, including that of children, and the environment, if confirmed, I commit to ensuring that registered pesticides do not cause unreasonable adverse effects to human health and the environment; to helping support and protect farmworkers and their families while ensuring pesticides are used appropriately among the nation's agriculture; and to using sound science in the decision-making process under the Federal Insecticide, Fungicide and Rodenticide Act.

EPA believes it is important to be responsive to petitions from the American public where there may be concerns regarding the safety of specific pesticide products. To respond to these concerns, EPA relies on the best available science and makes every effort to integrate our responses to petitions with our ongoing work under the registration and registration review programs.

Providing predictability on pesticide regulatory decisions is an important goal of the pesticide program. The Pesticide Registration Improvement Act (PRIA) provides a registration service fee system for applications for specific pesticide registration actions, which is designed to create a more predictable evaluation process for affected pesticide decisions. Regulatory decisions based on sound science is central to achieving this predictability. Moreover, I am committed to engaging with all stakeholders, listening to their concerns, and working collaboratively with them to enhance the robustness and certainty of the pesticide program.

2. Dr. Freedhof, as you know in 2016 Congress reformed TSCA on a bipartisan basis. I played a role in this from serving on the House Energy and Commerce Committee. At the time, it was viewed as a win-win for human and environmental health and timely review for product innovations by businesses. Significant fees are now assessed on industry in return for commitments on adequate staffing for efficient reviews. However, it is being reported that implementation of the 2016 reforms has been bumpy and is getting even bumpier at EPA. Chemical reviews have stalled, staff are unable to have meaningful dialogue with industry, extreme assumptions on risk are being made, and the best available science and real world data is not being incorporated. As a result, U.S. innovation is being stifled, putting American manufacturing at a competitive disadvantage.

   a. Are you committed to work with industry to get a clear, consistent, and timely process?

Response: The Senate EPW Committee showed leadership in passing much-needed changes to TSCA—America's primary chemical safety law. President Biden's *Executive Order 13990: Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis* requires EPA to review the last Administration actions, including risk evaluations for chemical substances under TSCA.

Since arriving at the Agency, I have met with numerous industry groups, and have repeatedly expressed my commitment to ensuring that the chemical safety office solicits industry data and other information, incorporates that information into our decision-making, and works to address industry concerns wherever possible. As I also said in my response to Chairman Carper related to worker safety, I believe that the Agency could improve upon its TSCA risk communications efforts in order to provide the appropriate context for its risk evaluations, and if confirmed, I commit to making that a priority.

If confirmed, I will work with all stakeholders, including industry, to implement strong chemical safety protections with a much-needed emphasis on safeguarding workers who manufacture or handle chemicals and reducing the potential disproportionate impact such chemicals have on people of color and low-income and indigenous communities.

Senator Lummis:

1. Does the EPA plan to alter existing or establish new mineralogical definitions? If so, will you commit to obtaining and incorporating input from mineralogical experts?

Response: I believe it is important for all public servants to be as transparent as possible to Congress and to the public as we look at information and develop decisions for moving forward.

If confirmed, I commit to conducting my office's work in a transparent manner, as we restore scientific integrity and evidence-based policymaking throughout EPA, including working with regulated entities; to using sound science in the decision-making process under our chemical safety programs; and to implementing those programs within their statutory requirements as written by Congress, including as we consider mineral forms such as in asbestos.

2. At your nomination hearing, you emphasized that EPA's decision-making will be transparent and well-documented. Do you commit to provide the same level of transparency and documentation to regulated entities throughout the risk evaluation and management process, including engaging with those entities while developing draft risk evaluations?

Response: I believe it is important for all public servants to be as transparent as possible to Congress and to the public as we look at information and develop decisions for moving forward.

Since arriving at the Agency, I have met with numerous industry groups, and have repeatedly expressed my commitment to ensuring that the chemical safety office solicits industry data and other information, incorporates that information into our decision-making, and works to address

industry concerns wherever possible. This transparency and documentation will be extended to all stakeholders, including regulated entities.

If confirmed, I commit to conducting my office's work in a transparent manner, as we restore scientific integrity and evidence-based policymaking throughout EPA, including working with regulated entities.

3. A lack of clear risk communication by EPA frequently creates public concerns over health and safety, many of which are the result of lack of information as opposed to actual risk to human health or the environment. What role does public perception play in EPA's decision-making?

Response: I believe it is important for all public servants to be as transparent as possible to Congress and to the public as we look at information and develop decisions for moving forward.

As I also said in my response to Chairman Carper related to worker safety, I believe that the Agency could improve upon its TSCA risk communications efforts in order to provide the appropriate context for its risk evaluations, and if confirmed, I commit to making that a priority.

If confirmed, I commit to conducting my office's work in a transparent manner, as we restore scientific integrity and evidence-based policymaking throughout EPA.

Senator Boozman:

1. The 2018 farm bill directed the Environmental Protection Agency (EPA), the Department of Interior's Fish & Wildlife Services, and the Department of Commerce's National Marine Fisheries Services ("Services") to establish an Interagency Work Group (IWG) to increase the timeliness and quality of Endangered Species Act species and habitat consultations for pesticides, develop a streamlined process for identifying which actions require consultations, and secure durable cooperation between the agencies. In recent public statements you said fixing the alignment of the Endangered Species Act (ESA) and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) is essential and if not fixed, will put EPA's ability to approve new crop protection products at risk to being shut down by the courts. If confirmed, do you commit to spending the time and energy it will take to work with your colleagues at the Services to substantially improve the ESA-FIFRA process, so that timely registration of crop protection products is more certain?
   a. If so, what are the three most important administrative reform ideas you plan to pursue?
   b. Do you support using the best available data and analyzing "what's likely vs. what's possible" when considering rates of use of pesticides?

Response: I believe it is possible to work with both the farming community and the environmental community to find common ground on protecting listed species and supporting local agricultural economies. If confirmed, I commit to working with EPA stakeholders to realize our shared goal of protecting listed species.

If confirmed, I look forward to working with the agricultural community and other stakeholder groups on how to chart a path forward.

2. It is essential for EPA to maintain an independent, predictable, science-based, and risk-based regulatory process to ensure the safety and efficacy of pesticides. EPA's Office of Pesticide Programs is staffed by expert scientists that work to ensure each registration label is underpinned by sound science with respect to human health and the environment. Unfortunately, the U.S. Court of Appeals for the Ninth Circuit has increasingly supplanted EPA's registration and registration review decisions instead of relying on the scientific analysis of EPA's career scientists. An example is the recent decision by the U.S. Court of Appeals for the Ninth Circuit issued on April 29, 2021, in the case of *League of United Latin American Citizens, et al. v. U.S. Environmental Protection Agency* concerning chlorpyrifos and other recent registrations undergoing legal challenge including glyphosate. In your view does the Ninth Circuit's increasing interest in renegotiating registrations from the bench pose as a threat to EPA scientific integrity, the work of its Office of Pesticides Program career staff, and EPA's existing registration processes?
   a. If confirmed, how will you work with EPA's Office of General Counsel and the Department of Justice to defend the Agency's science-based decisions on existing pesticide registrations?

   Response: Chlorpyrifos is a pesticide that is known to cause neurological harm at unsafe exposure levels and is of great concern especially to the farmworkers and their families. EPA is reviewing the decision as it considers its options regarding the decision.

   As the agency pursues its mission to protect human health, including that of children, and the environment, if confirmed, I commit to ensuring that registered pesticides do not cause unreasonable adverse effects on human health or the environment; to helping support and protect farmworkers and their families while ensuring pesticides are used appropriately among the nation's agriculture; and to using sound science in the decision-making process under the Federal Insecticide, Fungicide and Rodenticide Act.

3. The Pesticide Registration Improvement Act was signed into law in 2004 and was reauthorized in 2007, 2012 and 2019 – each time with the support of a diverse consortium of trade associations, non-governmental organizations, and state government officials. This legislation brought new, dedicated funds to the Environmental Protection Agency's Office of Pesticide Programs for more efficient pesticide registration and re-registration activities; it gave registrants certainty in the registration process after decades of uncertainty; it provided funding for farm worker education and training; and it brought needed funds for training for agricultural and healthcare workers. Over the past few years, due to resource constraints and other issues, the rate in renegotiated decision timeframes for pesticide regulatory reviews has increased significantly. Since the start of the fiscal year, EPA has renegotiated nearly 64% of all conventional pesticide decision deadlines, 24% of biopesticide decision deadlines, 6% of antimicrobial deadlines and over 28% of inert ingredient decision deadlines. In addition, there is a significant

backlog of smaller non-PRIA actions that are paid for by annual registrant maintenance fees on existing products. If confirmed, will you work to enact process improvements to address the significant renegotiation rates and the backlog of non-PRIA actions?

a. Further, if confirmed, will you continue efforts of past Assistant Administrators and convene all stakeholders including Congress, industry and the NGOs community with the goal of reauthorizing PRIA prior to October 1, 2023 to ensure EPA has the resources to complete timely pesticide registration and registration review decisions as efficiently as possible?

Response: Like past Assistant Administrators, I believe it is possible to work with both the farming community and the environmental community to find common ground on protecting human health and the environment and supporting local agricultural economies.

If confirmed, I look forward to working with the agricultural community and other stakeholder groups on how to chart a path forward.

4. EPA has an essential role in facilitating trade through harmonizing U.S. pesticide tolerances with Codex Maximum Residue Levels in the registration review process to renewing the Trilateral Working Group on pesticides under the Sanitary/Phytosanitary Committee on the new USMCA agreement. Importers of pesticide products manufactured in the U.S. require submission of both certificates of origin and certificates of registration issued by EPA, a process that needs improvements before it becomes an unnecessary trade barrier. If confirmed, do you commit to facilitating international trade for the industries regulated by EPA, including crop protection?

Response: I believe it is important for all public servants to be transparent with the Congress and the public as we look at information and develop decisions for moving forward.

If confirmed, I commit to conducting my office's work in a transparent manner, as we restore scientific integrity and evidence-based policymaking throughout EPA, including working with other countries and international organizations. I would look forward to being briefed on issues such as this related to improving EPA's pesticides programs and international trade.

5. In December 2020, the Mexican government issued a Presidential Decree stating the intent to eliminate the use, distribution, and importation of glyphosate in Mexico. The Decree, which is inconsistent with the U.S.-Mexico-Canada Agreement (USMCA), sound science, and other international sanitary/phyto-sanitary (SPS) standards, creates a dangerous potential precedent that could extend to other agricultural chemicals and negatively impact U.S. agricultural exports. If confirmed, do you commit to working with USTR and USDA to ensure our trading partners uphold their commitments, including scientifically sound SPS standards, related to crop protection tools under our trade agreements?

Response: I believe it is important for all public servants to be transparent with Congress and the public as we look at information and develop decisions for moving forward.

If confirmed, I commit to conducting my office's work in a transparent manner, as we restore scientific integrity and evidence-based policymaking throughout EPA, including working with other federal agencies, countries, and international organizations. I would look forward to being briefed on issues such as this related to improving EPA's pesticides programs and international trade.

6. On August 31, 2020, EPA published a proposed rule in the Federal Register (EPA-HQ-OPP-2019-0508) Pesticides; Exemptions of Certain Plant-Incorporated Protectants Derived from Newer Technologies, which was written by EPA career experts in the Office of Pesticide Programs' Biopesticides and Pollution Prevention Division. During the rule's subsequent 60 day public comment period, agricultural and technology stakeholders welcomed EPA's efforts to facilitate a more streamlined, science-based regulatory pathway for this technology, and those stakeholders provided targeted recommendations on ways to improve the proposed rule. Finalizing this rulemaking, consistent with the aforementioned stakeholders' recommendations, would help modernize EPA's regulatory approach to these technologies that could result in less water usage, less crop and food waste, and help combat climate change. Without this rule, there is not a consistent, workable regulatory pathway for these technologies. If confirmed, do you commit to ensuring EPA submits a final rule to the Office of Information and Regulatory Affairs at the Office of Management and Budget for interagency review as soon as possible?

Response: The rulemaking your question references continues to be an agency priority, as highlighted in EPA's regulatory agenda, and we are currently considering the comments received on the proposed rule with the goal of responding to those comments and issuing a final rule later this year.

If confirmed, I would look forward to working with colleagues at the U.S. Department of Agriculture on these issues, and more broadly, to working with stakeholders so that new technologies and innovations can be taken into account in our pesticides programs.

7. EPA's pesticide evaluation process is science-based and considers both the potential risks *and* benefits of pesticide products. The registration process includes risk assessments to ensure a product protects human health, including the health of children, the elderly, and immune-compromised individuals, the environment, and endangered species. Further, under the law EPA must reevaluate all registered pesticides at least every 15 years to ensure they continue to meet required safety standards. The current review cycle concludes October 1, 2022. This robust –science-based regulatory system is essential to providing consumers with assurance about the safety of pesticide products that are vital in protecting our nation's food supply, public health and safety, infrastructure, natural resources, and green spaces. Our regulatory process is also seen as the gold standard for the world and is required to meet World Trade Organization obligations. If confirmed, how will EPA strengthen and defend risk-based regulation and the science supporting its regulatory decisions?

Response: I firmly support EPA's risk-based approaches to pesticide assessments. If confirmed, I commit to continue to underscore the need for pesticide registration and reevaluation decisions that consider both hazard and potential exposure, and to conducting my office's work in a transparent manner, as we restore scientific integrity and evidence-based policymaking throughout EPA, including our pesticides programs.

8. Pests are harmful to our nation's food supply, public health, infrastructure, natural resources, and green spaces. Science-based integrated pest management (IPM) programs are used to manage mosquitoes, ticks, and rodents that carry disease; protect our nation's public utilities, rights-of-way, and infrastructure from invasive weeds; manage overgrowth and vegetation that pose fire hazards; and maintain homes, greenspaces, parks, sports fields, and golf courses. The definition of IPM is contained in three federal laws: (1) the 1996 Food Quality Protection Act (PL 104-170); (2) the Children's Health Act of 2000 (PL 106-310); and (3) the Food, Conservation, and Energy Act of 2008 (PL 110-234). These laws define IPM as "a sustainable approach to managing pests by combining biological, cultural, physical, and chemical tools in a way that minimizes economic, health, and environmental risks." IPM tries to reduce the risk of pests becoming a problem in the first place while having a specific plan of action to follow when pest populations reach a certain level. In the school environment, for example, this tolerance level may be quite low, or even "zero," in the case of rodents in school cafeterias. If confirmed, will EPA uphold the statutory definitions of IPM and ensure *all* essential pest control tools – biological, cultural, physical, and chemical – continue to be available to consumers, professionals, and those that maintain facilities such as schools, parks, athletic fields, day care centers, hospitals, and residences?

Response: As the agency pursues its mission to protect human health and the environment, if confirmed, I commit to ensuring that registered pesticides do not cause unreasonable adverse effects on human health and the environment; using sound science in the decision-making process under our pesticides programs; and implementing those programs within their statutory requirements as written by Congress.

While traditional pest control involves the routine application of pesticides, IPM focuses on pest prevention and only using pesticides as needed. This provides a more effective, environmentally sensitive approach that combines biological, cultural, physical, and chemical tools to minimize risks associated with pests and pesticides.

9. Effective pest and rodent control is essential to protecting the health and well-being of our families and communities, regardless of socioeconomic circumstances. Mosquitoes, for example, can carry West Nile virus, Zika virus, Eastern Equine Encephalitis, and yellow fever. Ticks can carry Lyme disease and Rocky Mountain spotted fever. According to the CDC, rodents directly transmit eleven serious diseases (including Hantavirus pulmonary syndrome, plague, and tularemia), and indirectly transmit even more. Whether pest control is undertaken by a professional or a consumer, pesticide products are a crucial component of managing pests and protecting public health at home, school, work, and play. If confirmed, how would you promote greater efficiency in the Office of Pesticide Programs, so these essential products are effectively managed through

the regulatory process that follows FIFRA's risk-benefit standards and fully considers the benefits of the non-agricultural pesticides used to control mosquitoes, ticks, rodents, termites, and plant diseases?

Response: Federal law requires EPA, in coordination with Centers for Disease Control and Prevention (CDC) and the U.S. Department of Agriculture (USDA), to identify pests of significant public health importance and in coordination with the Public Health Service, to develop and implement programs to improve and facilitate the safe and necessary use of chemical, biological, and other methods to combat and control such pests of public health importance. I believe it is vital to continue this work and to collaborate with the pest control industry and the environmental community to find common ground on protecting human health and the environment and controlling dangerous pests.

If confirmed, I look forward to working with the pest control industry and other stakeholder groups on how to chart a path forward.

10. In November 2020, EPA released its draft Biological Evaluation (BE) for public comment on atrazine, simazine and propazine, three widely-used herbicides used to control a variety of grasses and broadleaf weeds. EPA's comment period closed in February 2021, but EPA has not yet published the final BE. If confirmed, what will you do to ensure all reliable and available science, with respect to both exposure and toxicity, is fully assessed and used to impact the final BE on this crucial technology product group?
    a. Further, if confirmed, what steps will you take to ensure full consideration is given to the data alluded to in the paper "Grounds for an Atrazine Ecological Endpoints Update," submitted to EPA by a group of farm organizations on December 15, 2020?

Response: I believe it is possible to work with both the farming community and the environmental community to find common ground on protecting listed species and supporting local agricultural economies.

If confirmed, I commit to considering all input received as we consider whether to make any scientifically supportable changes to the biological evaluation for atrazine, simazine, and propazine before any initiation of consultation with the Services.

I believe it is important for all public servants to be as transparent with the Congress and the public as we look at information and develop decisions for moving forward. If confirmed, I commit to conducting my office's work in a transparent manner, as we restore scientific integrity and evidence-based policymaking throughout EPA, including our pesticides programs.

11. In addition to serving on EPW, I am also honored to serve as the Ranking Member on the Senate Agriculture, Nutrition & Forestry Committee, which has primary oversight over FIFRA and EPA's work related to pesticides. If confirmed, do you commit to appearing before the Senate Agriculture, Nutrition & Forestry Committee on issues related to EPA's administration and implementation of FIFRA-related activities?

Response: If confirmed I would look forward to working with the Senate Agriculture Committee on pesticides issues.

Senator Wicker:

1. The Pesticide Registration Improvement Act (PRIA) was signed into law in 2004 and was reauthorized in 2007, 2012 and 2019, each time with the support of a diverse group of stakeholders. This legislation brought new, dedicated funds to the Environmental Protection Agency's (EPA) Office of Pesticide Programs for more efficient pesticide registration and re-registration activities. It also gave registrants certainty in the registration process after decades of uncertainty, and it provided funding for farm worker education and training. Due to resource constraints and other issues, the rate in renegotiated decision timeframes for pesticide regulatory reviews has jumped significantly in the past few years. Since the start of Fiscal Year 2021, EPA has renegotiated nearly 64% of all conventional pesticide decision deadlines, 24% of biopesticide decision deadlines, 6% of antimicrobial deadlines and over 28% of inert ingredient decision deadlines. In addition, there is a significant backlog of smaller non-PRIA actions that are paid for by annual registrant paid maintenance fees on existing products. If confirmed, will you work to enact process improvements to address the significant renegotiation rates and the backlog of non-PRIA actions?

    a. If confirmed, will you also continue the efforts of past Assistant Administrators and convene all stakeholders including Congress, industry and non-governmental organizations to reauthorize PRIA prior to the start of Fiscal Year 2024 to ensure EPA has the resources needed to complete timely pesticide registration and registration review decisions efficiently?

Response: Like past Assistant Administrators, I believe it is possible to work with both the farming community and the environmental community to find common ground on protecting human health and the environment and supporting local agricultural economies.

If confirmed, I look forward to working with the agricultural community and other stakeholder groups on how to chart a path forward.

2. EPA's pesticide evaluation process is science-based and considers both the potential risks and benefits of pesticide products. The registration process includes risk assessments to ensure that the product protects human health, including the health of children, the elderly, and immune-compromised individuals, the environment, and endangered species. In addition, the law requires EPA to reevaluate all registered pesticides at least every 15 years to ensure they continue to meet required safety standards. The current review cycle concludes October 1, 2022. This robust-science based regulatory system is essential to providing consumers with assurance about the safety of pesticide products that are vital for protecting our nation's food supply, public health and safety, and natural resources. Our regulatory process also is considered the gold standard globally and is required to meet World Trade Organization obligations. If confirmed, how will EPA, under your

leadership, strengthen and defend risk-based regulation and the science supporting its regulatory decisions?

Response: I firmly support EPA's risk-based approaches to pesticide assessments and the need for pesticide registration and reevaluation decisions that consider both hazard and potential exposure.

If confirmed, I commit to conducting my office's work in a transparent manner, as we restore scientific integrity and evidence-based policymaking throughout EPA, including our pesticides programs.

3. The 2018 Farm Bill directed EPA, the U.S. Fish and Wildlife Service, and the National Marine Fisheries Service to establish an Interagency Work Group to increase the timeliness and quality of Endangered Species Act (ESA) species and habitat consultations for pesticides. The legislation also required EPA and the Services to develop a streamlined process for identifying which actions require consultations and to secure durable cooperation between the agencies. In recent public statements, you have mentioned that fixing the alignment of the Endangered Species Act and FIFRA is essential, and the ability of EPA to approve new crop protection products is at risk to be shut down by the courts if not fixed. If confirmed, do you commit to working with your colleagues at the U.S. Fish and Wildlife Service and the National Marine Fisheries Service to avoid a programmatic stoppage?

Response: If confirmed, I commit to continuing to work with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service to carry out the requirements of the 2018 Farm Bill.

Senator Ernst:

1. You have spoken about your commitment to scientific integrity. I applaud your focus on that; it is indeed critical to ensure that every decision EPA makes is based on sound science. I know you also understand as well as anyone that the regulation of pesticides in this country is risk-based, and that FIFRA, the primary law governing pesticide regulation, also requires EPA to balance any risks of a pesticide with its benefits. There is a class of selective herbicides that cattle producers and other land managers in my state and across the country have used successfully for decades to manage noxious/invasive weeds and improve pasture/rangeland health. EPA has recently published decisions/proposals involving products in this class of chemicals that show a pretty striking overemphasis on a very narrow set of potential hazards/perceived risks related to agricultural waste and its use in compost and a woefully insufficient regard for the very real benefits of the products in question, including the many risks that pesticide products reduce or eliminate. I'm concerned that without a course correction, cattle producers in my state and across the country may lose the flexibility they need to use these products. I'm especially concerned that the direction EPA is going could limit cattle producers' options during times of drought or other natural disasters – threatening not only their bottom line but the welfare of their animals. Decisions that rely on sound

science incorporate all available information, including the considerable benefits from pesticides, and rely on data to assess risk, not inaccurate default assumptions. How will you improve the quality of EPA's pesticide reviews to more accurately reflect the underlying science on a pesticide product's benefits and risks?

Response: If confirmed, I commit to conducting my office's work in a transparent manner, as we restore scientific integrity and evidence-based policymaking throughout EPA, including using the best available science. Regarding your concern about EPA pesticide decisions limiting cattle producers' option, if confirmed, I look forward to working with the agricultural community and other stakeholder groups on how to chart a path forward. I believe it is possible to work with both the farming community and the environmental community to find common ground on protecting human health and the environment and supporting local agricultural economies.

2. Pesticides are of critical importance to agriculture and enable a safe and reliable food supply. EPA's pesticide registration process is a long-standing, efficient process that has garnered bipartisan support regardless of administration for enabling responsible pesticide use. Managing this program effectively means ensuring that farmers and ranchers have the crop protection tools they need. How do you plan to manage this program and do you anticipate any major changes to the program?

Response: I believe it is possible to work with both the farming community and the environmental community to find common ground on protecting human health and the environment and supporting local agricultural economies.

If confirmed, I look forward to working with the agricultural community and other stakeholder groups on how best to manage EPA's pesticides programs.